

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	: Bolduc, et al.	Confirmation No.:	8124
Serial No.	: 10/628,920	Art Unit	: 3734
Filed	: July 29, 2003	Examiner	: C. Gettman
Title	: Methods and Devices for Maintaining a Cardiopulmonary Bypass and Arresting a Patient's Heart		

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February 4, 2008

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**APPEAL BRIEF**

Dear Sir:

This Appeal Brief is filed in response to the Notice of Appeal, which was mailed by Applicant to the U.S. Patent & Trademark Office on September 4, 2007, the time for filing having been extended by petition.

**Real Party In Interest:**

The real party in interest for this patent application is Heartport, Inc., Somerville, NJ, USA.

**Related Appeals and Interferences:**

There are no related appeals or interferences known to Appellant, the Appellant's legal representative, or the Assignee that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**Status of Claims:**

Claims 58-72 are pending. Claims 70-72 are allowed. Claims 58-69 have been finally rejected, and are hereby appealed.

**Status of Amendments:**

No amendments have been filed after the final rejection of March 29, 2007.

**Summary of Claimed Subject Matter:**

The subject matter claimed in independent claim 58 is a method of forming an anastomosis by placing a lumen of a graft vessel in fluid communication with a lumen of a target vessel through an opening in a wall of the target vessel. One embodiment of the claimed method is described generally at page 24, line 30 through page 25, line 19 of the originally filed application (paragraph 0083 of U.S. Application Publication No. 2004/0073240, and is depicted at Figures 13A-13C.

The first step of the claimed method is to provide a plurality of clips that have certain features. Examples of inventive clips are element numbers 192 in Figures 13A-13C and Figures 12A-12G, for example. The clips are made of a superelastic material (see page 24, lines 16-24), and each of the plurality of clips has a first end and a second end. For example, Figure 12A depicts a first end (sharp distal point 198) and a second end (proximal extremity 195); similarly, Figure 12F depicts a first end (220a) and a second end (220b). The clips have a first configuration, where the first end and second end are spaced apart so as to be able to

receive therebetween a portion of the graft vessel and a portion of a target vessel tissue proximate the opening in the wall of the target vessel. See Figures 13A-13C all shown in a first configuration. The clips have a second configuration, where the portion of the graft vessel and the portion of the target vessel are approximated. See Figures 12D and 12G.

The method continues with the following steps. The first end of each of the plurality of clips is positioned through the opening in the target vessel. Figure 13B shows an opening, indicated by the letter O, in a target vessel, indicated by the letter T. A plurality of clips are positioned through the opening O as depicted in Figures 13B and 13C. The first end of each of the plurality of clips is passed through an inner wall of the target vessel while the clips are in the first configuration. See Figure 13C where the clips are shown as having been positioned through the opening O and then the first end 196 of each of the clips is passed through the inner wall of the target vessel T. Another step is to pass at least a portion of each of the plurality of clips through the graft vessel. See Figure 13A and 13B, where at least a portion of each of the plurality of clips 192 are passed through a graft vessel, indicated by the letter G.

Finally, the plurality of clips is permitted to assume the second position to approximate the graft vessel and the target vessel. The last step is described at page 25, line 14-16, where it is described that the vessel walls (target and graft vessel walls) are compressed between barbs 202 (first end) and proximal extremities 195 (second end). Specifically, the superelastic clips are described on page 24, lines 16-24, as moving from a first configuration to a second configuration, either through the application of heat (lines 20-24) or by holding the clip in an open, first configuration, and then permitting the clip to move to the second configuration by no longer holding the clip in an open position (lines 17-20).

**Grounds of Rejection to be Reviewed on Appeal:**

Whether the final rejection stating that claims 58-69 are unpatentable under 35 U.S.C. 103(a) over U.S. Patent No. 4,809,695 (Gwathmey) in view of U.S. Patent No. 5,330,503 (Yoon) should be reversed.

**Argument:**

Appellant submits that the claimed invention is not obvious in view of the Examiner's combination of Gwathmey and Yoon as neither Gwathmey nor Yoon set forth each and every element of claim 58, and therefore the claimed invention can not be held to be obvious.

With reference to claim 58 in the Appendix, claim 58 requires the steps of (a) positioning the first end of each of the plurality of clips through the opening in the target vessel and (b) passing the first end of each of the plurality of clips through an inner wall of the target vessel while the clips are in the first configuration. The clips of Gwathmey are not positioned *through an opening in a target vessel*; nor are the first ends of each of the plurality of clips passed through an inner wall of the target vessel *while the clips are in the first configuration*.

First, focusing on the step labelled as (a) above, Gwathmey does not position clips through an opening in a target vessel. Figure 18 of Gwathmey depicts an end-to-end anastomosis of two blood vessel segments, where the edges of the two blood vessel segments are everted and a clip 116 is placed about the two everted edges (see column 7, lines 13-20). The clip is then deformed under a force applied by pliers (see Figures 11-15) so as to force the clip into the configuration shown in Figure 19. Gwathmey does depict an end-to-side anastomosis in Figures 22 and 23, however, there is no teaching that the first ends of the clips are positioned through an opening in the target vessel. Further, this step is not taught or suggested by Gwathmey.

Second, focussing on the step labelled as (b) above, Gwathmey does not pass the first ends of each of the plurality of clips through an inner wall of the target vessel while the clips are in the first configuration. As shown in Figure 18 of Gwathmey, the clips are depicted in a first configuration. That is the first end and the second end of the Figure 18 Gwathmey clips are spaced apart so as to be able to receive therebetween a portion of the graft vessel and a portion of a target vessel tissue proximate the opening in the wall of the target vessel. However, the first end of the clips is not passed through the inner wall of the target vessel while the clips are in the first configuration.

Instead, the first end of the Gwathmey clip is passed through an inner wall as the clip is deformed by the pliers into a configuration shown in Figure 19. Such a configuration is not the first configuration claimed in step (b). Referring to Figure 13C of the current application clearly depicts the difference between the claimed invention and what is shown in Gwathmey. The clips of the current invention remain in the first configuration as they are passed through the inner wall of the target vessel. That is simply not the case with Gwathmey.

Further, neither Gwathmey nor Yoon describe a superelastic clip. The Examiner takes the position that Gwathmey teaches all the steps except that “Gwathmey is silent on the material of the clip”. The Examiner relies on Yoon to provide that element, stating that Yoon “teaches a clip made out of a flexible coil”. Referring to Figure 7 and column 7, lines 51-59, Yoon describes “a suture device made of a flexible bioabsorbable material ....” While the suture device shown in Figure 7 is described as flexible, Yoon does not describe a superelastic material, such as nitinol, that would permit the clip to move to a second position from a first position, where the ends of the clip are spaced apart, when a force that holds the clip in the first position is removed. Thus, neither Gwathmey (as admitted by the Examiner) nor Yoon teach a superelastic clip, and therefore the providing step is not supplied.

**Conclusion:**

As such, for the reasons discussed above, Appellant maintains that the Examiner's final rejection of claims 58-69 as being unpatentable should be reversed.

Respectfully submitted,

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Dated: February 4, 2008

**APPENDIX**

1-57. (Cancelled)

58. (Previously Presented) A method of forming an anastomosis by placing a lumen of a graft vessel in fluid communication with a lumen of a target vessel through an opening in a wall of the target vessel, comprising the steps of:

providing a plurality of clips, the clips being made of superelastic material, each of the plurality of clips each having a first end and a second end, a first configuration, where the first end and second end are spaced apart so as to be able to receive therebetween a portion of the graft vessel and a portion of a target vessel tissue proximate the opening in the wall of the target vessel, and a second configuration, where the portion of the graft vessel and the portion of the target vessel are approximated;

positioning the first end of each of the plurality of clips through the opening in the target vessel;

passing the first end of each of the plurality of clips through an inner wall of the target vessel while the clips are in the first configuration;

passing at least a portion of each of the plurality of clips through the graft vessel; and

permitting each of the plurality of clips to assume the second position to approximate the graft vessel and the target vessel.

59. (Previously Presented) The method of claim 58, wherein the second passing step comprises passing the first end of each of the plurality of clips through an outer wall of the graft vessel.

60. (Previously Presented) The method of claim 59, wherein the passing step of claim 59 occurs prior to the positioning step of claim 58.

61. (Previously Presented) The method of claim 58, comprising the step of positioning one end of each clip through the graft vessel at radially spaced locations about the graft vessel.

62. (Previously Presented) The method of claim 58, wherein each clip of the plurality of clips is separately passed through the graft vessel.

63. (Previously Presented) The method of claim 58, comprising compressing the graft vessel and the target vessel together when at least one of the plurality of clips is in the second configuration.

64. (Previously Presented) The method of claim 58, wherein each clip of the plurality of clips independently approximates the graft vessel and the target vessel when each clip of the plurality of clips is in the second configuration.

65. (Previously Presented) The method of claim 58, wherein at least one of the first end and the second end of the plurality of clips cross over one another when moving from the first configuration to the second configuration to form an enclosed space to retain a portion of the graft vessel and a portion of the target vessel.

66. (Previously Presented) The method of claim 58, wherein each clip is isothermally transformed from the first configuration to the second configuration.

67. (Previously Presented) The method of claim 58, wherein each clip of the plurality of clips is restrained in the first configuration.

68. (Previously Presented) The method of claim 58, comprising, prior to the permitting step, releasing each clip of the plurality of clips from the first configuration.



69. (Previously Presented) The method of claim 68, wherein the releasing step is performed using one of a needle driver and forceps.

70. (Previously Presented) A method of forming an anastomosis by placing a lumen of a graft vessel in fluid communication with a lumen of a target vessel through an opening in a wall of the target vessel, comprising the steps of:

providing a plurality of clips, the clips being made of superelastic material, each of the plurality of clips each having a first end and a second end, a first configuration, where the first end and second end are spaced apart to receive therebetween a portion of the graft vessel and a portion of a target vessel tissue proximate the opening in the wall of the target vessel, and a second configuration, where the portion of the graft vessel and the portion of the target vessel are approximated;

coupling each of the plurality of clips to a band;

passing each of the plurality of clips through the graft vessel and the target vessel; and

permitting each of the plurality of clips to assume the second configuration to approximate the graft vessel and the target vessel..

71. (Previously Presented) The method of claim 70, comprising the step of severing the band.

72. (Previously Presented) The method of claim 71, comprising the step of removing the band from each of the plurality of clips.

**EVIDENCE APPENDIX**

No evidence has been submitted by Appellant pursuant to 37 C.F.R. §§ **1.130**, **1.131**, or **1.132** during the prosecution of this application. Nor has any other evidence been entered by the Examiner and relied upon by Appellant in the appeal.

**RELATED PROCEEDINGS APPENDIX**

Pursuant to 37 C.F.R. 41.37(c)(1)(ii), Appellant, the Appellant's legal representative, or the Assignee is not aware of any decisions that have been rendered by a court or the Board in any proceeding that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.